

Audit of the Operational Delivery Division

Official Controls of FBOs' Procedures Based on HACCP Principles.

Audit Programme: 2024/2025
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Foreword

This audit is part of the annual programme of internal audits directed at the official food and feed controls delivered by Food Standards Scotland as the competent authority and is carried out by Food Standards Scotland's Audit Assurance Division.

These assess conformance against Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law and the associated planned arrangements.

Article 6 of this Regulation requires that to ensure compliance with the Regulation competent authorities shall carry out internal audits or have audits carried out themselves and shall take appropriate measures in the light of the results of those audits.

The audit scope was detailed in the audit brief and plan issued to the Operational Delivery Division on 20th September 2024.

The aim of the audit is to maintain and improve consumer protection and confidence by ensuring that the Operational Delivery Division is providing effective delivery of official controls and enforcement of HACCP based procedures in those approved establishments under Food Standards Scotland's remit.

The audit scheme also provides the opportunity to identify and disseminate good practice and provide information to inform Food Standards Scotland's policy on food safety, standards and feeding stuffs.

Specifically, this audit aimed to establish:

- Verification that official controls are carried out in compliance with planned arrangements.
- Verification that planned arrangements are applied effectively.
- Verification that planned arrangements are suitable to achieve the objectives of official controls.

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1.0 Introduction

- 1.1 Hazard Analysis and Critical Control Points (HACCP) is a globally recognised, systematic and science-based approach to food safety that addresses hazards throughout the food chain from primary production to final consumption. It focuses on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing.
- 1.2 HACCP Principles are generally considered and internationally recognised to be useful self-check system for Food Business Operators (FBOs) to control hazards that may occur in food. These principles are summarised in [Annex B](#).
- 1.3 Article 5 of Regulation (EC) No 852/2004 requires Food Business Operators to put in place, implement and maintain a permanent procedure or procedures based on HACCP principles. FBOs should develop and operate food safety management systems and procedures grounded in these principles.
- 1.4 The Official Controls Regulation (OCR) outline the requirements of the Competent Authorities in the delivery of Official Controls.
- 1.5 In addition to the general requirements cited in Regulation (EU) 2017/625, Article 5, it is also stated that Official Control methods and techniques shall include an assessment of procedures based on the principles of hazard analysis critical control points (Article 14). Furthermore, official controls performed in relation to the production of meat shall include the verification of compliance with the requirements applicable to audits of good hygiene practices and procedures based on HACCP principles (Article 18).
- 1.6 This reports highlights the key findings and conclusions drawn from the assessment of official controls delivered by Food Standards Scotland (FSS) through the Operational Delivery Division to verify FBOs' compliance with HACCP based procedures requirements.
- 1.7 The overarching criteria which detail the standards that the assessment has been made against are contained within the relevant sections of:
 - [Regulation \(EU\) No 2017/625](#)
 - [Commission Implementing Regulation \(EU\) 2019/627](#)
 - [Regulation \(EU\) No 852/2004](#)
 - [Regulation \(EU\) No 853/2004](#)
- 1.8 The planned arrangements assessed with regards to the delivery of these criteria were primarily contained within:
 - The Scottish Manual for Official Controls and internal procedures provided by the Operational Delivery Division.
- 1.9 This audit was planned as a combination of documentary assessment, remote interview of FSS staff responsible for the operational management of the service, and on-site reality checks.

- 1.10 The on-site verification element took place within one stand-alone cutting plant located in Operational Delivery Area 2, and another one in Area 3. The selection criteria were based on a number of relevant operational factors and aimed to provide a level of assurance on the appropriateness, consistency and effectiveness of the delivery of these official controls across Scotland.

Reason for the Audit

- 1.11 As detailed in the Foreword, Article 6 of retained Regulation (EU) 2017/625 requires Competent Authorities to carry out internal audits or have audits carried out on themselves.
- 1.12 The audit programme covering the official controls delivered by FSS is carried out as an internal audit by FSS's Audit Assurance Division. This audit forms part of that audit programme.
- 1.13 An internal audit covering some of the subjects within the scope of this audit was commissioned to, and delivered by, the Food Standards Agency Audit Assurance Team in October 2018. The title was "The Officials role in Hazard Analysis and Critical Control Point (HACCP) systems at approved establishments under Veterinary control in Scotland". The audit opinion was "moderate".
- 1.14 Since 2018 there have been significant regulatory changes with the introduction and implementation of the OCR in 2019. Additionally, the Operational Delivery Division has since adopted a new approach to verifying compliance with FBOs' HACCP-based procedures in those establishments under their remit.

Scope of the Audit

- 1.15 It was agreed that the audit scope would cover:
- A review and assessment of those arrangements, policies and procedures developed/adopted by the Operational Delivery Division to discharge their obligations.
 - An assessment of the capacity and capability to deliver these official controls.
 - An assessment and verification of the implementation of those arrangements and procedures.
 - The identification and dissemination of good practice.
 - The provision of information to aid future FSS policy and operational development.

2.0 Executive Summary

- 2.1 Auditors recognised that HACCP based procedures verification is embedded in the daily input of the FSS team in plants with daily attendance in addition to the controls delivered as part of the Audit of FBOs programme in all establishments.
- 2.2 The procedures and arrangements detailed in the Scottish Manual for Official Controls are current, extensive and clear. Operational updates are issued as needed, ensuring that all staff members are informed of any changes.
- 2.3 Since 2020/21 the Operational Delivery Division has adopted the Official Control Verification methodology and approach for the delivery of the audit programme. We found that this approach has facilitated a more focussed and targeted manner to assess compliance with HACCP based procedures' requirements, particularly in establishments with complex processes, large HACCP Plans documentation and lower compliance levels, compared to the previous one-day audit system.
- 2.4 There appears to be adequate staff capacity to deliver the established official controls intervention program. Our findings indicate that establishments have received the minimum of three official controls interventions per annual cycle, as outlined in the planned arrangements. The Establishment Live Report (ELR) for each establishment contains records demonstrating that the FBO HACCP-based procedures obligations were assessed during these interventions.
- 2.5 The audit found that planned arrangements are generally adequate but there are some areas for improvement which could enhance the effectiveness and efficiency of some of the processes. These are around Objective Connect, Unannounced Inspections (UAs) and the audit cycle intervals.
- 2.6 Objective Connect is the platform chosen by Operational Delivery as means for the FBOs to upload and share their Food Safety Management System and evidence with FSS officers. We recognise this concept of sharing information between FBOs and FSS as an area of "good practice" developed by Operational Delivery. It has the potential to assist, inform and direct officers during the official controls interventions programme, to provide record/evidence for retention and continuity, and reduce the burden to the FBOs. This audit highlights some areas for enhancement around the use of Objective Connect to maximise its full potential and objectives.
- 2.7 UAs introduce an unannounced inspection element to official controls at cutting plants and game handling establishments. One of their aims is to support the FSS Veterinary Auditors during the audit cycle as an important tool to provide evidence of continuous application of HACCP based procedures by FBOs. While we recognise the significant effort and logistics involved in the delivery of this programme by Operational Delivery, we believe there are opportunities to enhance its effectiveness and consistency as per planned arrangements.
- 2.8 The audit confirmed that the ongoing training not only meets but, in some cases, could be considered exceeding FSS obligations for the topic audited. All Official Veterinarians and Meat Hygiene Inspectors have been trained to HACCP level 3 as

part of their standard qualification pathway. We found that approximately 60% of all OVs have attained HACCP level 4 qualifications, and this is the case for all MHIs involved in the delivery of UAIs.

- 2.9 The audit has noted several areas of “good practice” through the report and provided feedback given by the FBOs in the establishments visited.

Level of Assurance

- 2.10 The audit’s assurance category has been assigned as below. The four assurance categories are shown in Annex C.

- 2.11 In providing this audit opinion we recognise that our findings represent a considerable improvement and a positive response to the 2018 audit findings.

<p>Reasonable Assurance</p> <p>Controls are adequate but require improvement.</p>	<p>Some improvements are required to enhance the adequacy and effectiveness of procedures. There are weaknesses in the risk, governance and/or control procedures in place but not of a significant nature.</p>
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3.0 Audit Findings

- 3.1 [Article 5. General obligations](#)

Planned arrangements

- 3.2 Procedures and arrangements are detailed in Chapter 4 of the Scottish Manual for Official Controls (SMOC). This was found current, extensive and clear in content for their purpose. Operational updates to this chapter have been issued to all staff members through action notes when needed.
- 3.3 HACCP based procedures requirements in those approved establishments with full Authorised Officer’s (AOs) attendance i.e. slaughterhouses and game handling establishments, are verified and enforced on a daily basis by an Official Veterinarian (OV), assisted by Meat Hygiene Inspectors (MHIs) when present, as part of their routine duties. These actions are recorded and inform the Operational Delivery Audit Team when conducting audits of good hygiene practices and procedures based on HACCP principles.

- 3.4 Cutting Plant establishments do not require daily AOs' attendance, therefore, the verification of compliance with HACCP based procedures requirements is delivered within the audit programme for each establishment.
- 3.5 In those establishments which require approval, the verification of HACCP based procedures is completed during the approval determination period and before full approval is granted. This was supported by random checks on establishments newly approved. Once an establishment is approved, it is enrolled within the routine audit programme.
- 3.6 Since 2020/21 the Operational Delivery Division has adopted the Official Control Verification (OCV) methodology for the audit programme. The OCV approach has therefore become the method for assessing HACCP implementation, and has itself become a critical control point in the delivery of audits as a result.
- 3.7 We found that this approach has facilitated a more focussed and targeted manner to assess compliance with HACCP based procedures requirements, particularly in establishments with complex processes, extensive HACCP Plans documentation and lower compliance, compared to the previous one-day audit system.

Capacity and competence

- 3.8 There are currently three experienced FSS dedicated Veterinary Auditors responsible for delivering the bulk of HACCP based procedures verification assessments across all 94 approved establishments through the audit programme. They retain overall responsibility and leadership in the assessment of compliance at each establishment and are supported in this task by other operational staff members, including Veterinary Advisors, OVs and MHIs, as appropriate.
- 3.9 We found that establishments have received a minimum of three official control interventions per annual cycle, during which the FBO HACCP-based procedures obligations have been assessed as per evidenced contained in the Establishment Live Report (ELR) for each establishment. The number of interventions in slaughterhouses on the islands is lower due to a risk based approach and logistical accessibility.
- 3.10 Operational Delivery has established a minimum of three official controls interventions spread over a period of 12 months for all FSS establishments, with all the inspections forming part of a yearly audit cycle. There appears to be sufficient staff capacity to deliver these planned arrangements.
- 3.11 However, as an area for consideration, we found inconsistencies in the gap intervals between the end and commencement of each audit cycle, with some gaps extending to five months or more without a clear pattern or explanation. This is not a consistent reflection of the planned arrangements and should be reviewed. ([Recommendation 1](#)).

Recommendation 1

Review of the current gap intervals between the end and commencement of each audit cycle to ensure consistency with planned arrangements.

- 3.12 On a practical delivery level, interviewed field staff members involved in the delivery of UAIs expressed concerns regarding their confidence and ability to properly assess FBOs' HACCP systems if needed. Consequently, this verification task appears to be predominantly handled by Veterinary Auditors as evidenced through the review of a representative number of ELR reports across all FSS Operational Delivery areas. This situation may indicate potential gaps in mentoring or experience at UAI level, particularly for those staff members who are not familiar with HACCP Plans and these verification tasks as part of their daily routine, such as MHIs. We consider there could be clear benefits in reducing this gap with the primary aim being to enhance the overall effectiveness and consistency of the processes as per planned arrangements. See overall ([Recommendation 3](#)) related to UAIs.

Training

- 3.13 The audit confirmed that the ongoing training not only meets but, in some cases, could be considered exceeding FSS's obligations of the topic audited. Training is part of the portfolio of one of the Veterinary Advisors and there is evidence of this being well structured and managed.
- 3.14 While all field staff members have been trained to an equivalent HACCP 3 level through the OV/MHI qualification courses, approximately 60% of OVs and all MHIs involved in UAIs have gained further HACCP level 4 qualifications. Additionally FSS Auditors and Veterinary Advisors have obtained Lead Auditor qualification based on ISO standards, and have completed an OCV specialised course.
- 3.15 One of the Veterinary Auditors manages the HACCP portfolio. There is evidence of regular meetings with Food Standards Agency colleagues to discuss HACCP issues and opportunities to enhance the appropriateness, consistency and effectiveness in the delivery of official controls in this area of work.

Review of operational delivery/reality checks.

- 3.16 The announced and "classic" unannounced elements of the FSS official controls intervention programme were observed as part of the reality verification checks of this audit. While the announced intervention visit was specifically focused on the verification/validation of the FBO's HACCP Plan and its implementation, the unannounced intervention primarily covered the implementation of some of the Pre-requisites/Operational Pre-requisites identified by the FBO following HACCP principles. We consider that this dual approach has the potential to ensure comprehensive coverage of both planned and operational aspects of food safety and highlight this as an area of good practice implemented by Operational Delivery.

- 3.17 Objective Connect is the platform chosen by Operational Delivery for the FBOs to upload and share relevant documentation with FSS prior to and between official controls interventions. Documents submitted by the FBO through Objective Connect are automatically mirrored in each establishment's eRDM file for easy access.
- 3.18 This concept of sharing documentation between FSS and FBOs is recognised by auditors as an area of "good practice" identified by Operational Delivery. It has the potential to assist, inform and direct officers during official controls interventions, provide record/evidence for retention and continuity, and reduce the burden on FBOs. We consider these areas of particular relevance and crucial when assessing the HACCP Plan and associated documentations/records, especially in more complex and less compliant establishments.
- 3.19 However, during the announced intervention visit, it was evident that the officer spent a significant amount of time on-site asking for and assessing parts of the FBO's HACCP Plan that had not been uploaded or were not readily accessible / current in Objective Connect prior to the intervention visit. Had the documentation been available to the auditor prior to the visit, we consider that this intervention would have been more time-efficient.
- 3.20 Also, in relation to the unannounced intervention visit, the officers expressed a limited understanding in the use of eRDM. Consequently, this platform is not being utilised as part of their preparation for the intervention. This limitation restricts the officers' ability to familiarise themselves with FBO documentation prior to the intervention, when appropriate.
- 3.21 On reviewing Objective Connect through the plant files mirrored in eRDM for the two establishments selected, coupled with a representative number of establishments in each operational area, auditors found that in most cases, these plant files could benefit from an enhanced document control management system and extended content / number of documents available. Overall we found that navigating through the folders and documents was not easy.
- 3.22 Therefore, while we acknowledge the significant efforts made by Operational Delivery in communicating, educating and requesting the FBOs for updates/uploads in Objective Connect, and also recognising that this platform provides a valuable tool to officers and FBOs, we consider that work could be done at both FSS and FBO levels to enhance its full potential and subsequently the effectiveness and efficiency in the verification of procedures based on HACCP principles. By addressing these areas we consider that FSS and FBOs can better leverage Objective Connect to support the official controls interventions, reduce the burden on FBOs and ensure thorough and efficient assessments of HACCP-based procedures ([Recommendation 2](#)).

Recommendation 2

Review the use of Objective Connect/eRDM at both FSS and FBO levels to enhance the efficiency and potentially effectiveness of processes directed at verifying FBO procedures based on HACCP principles.

- 3.23 During the announced intervention visit, the auditors were very pleased with the thorough interrogation of the HACCP Plan and the use of various OCV tools to validate and verify its implementation.
- 3.24 With regards to the unannounced intervention visit, the auditors identified relevant findings and areas for improvement to enhance this part of the official controls programme. These main findings are detailed below;
- Liaison and communication: Prior to the inspection visit, there was no liaison between the UAI officers and FSS auditors to discuss or direct the scope of the intervention, and how best to support and inform the overall delivery of the official controls in this particular establishment. Under these circumstances, the scope of the inspection visit was selected by the UAI officers with the main criteria being the enforcement programme and those systems which had not been previously verified by the Veterinary Auditors. It is noteworthy that the UAI officers informed us they had not previously been to this particular establishment.
 - As stated in the SMOC, UAIs are now part of the audit cycle and officers are to take an overall view of the operating practices on the day of the inspection to verify FBO's implementation of those procedures based on HACCP Principles. These reality checks were completed mostly effectively and efficiently. However these officers also conducted more detailed verification exercises on the procedures, documents and records related to the audited systems. We consider that these full verification exercises were not conducted with the same level of scrutiny and effectiveness as those observed during the announced inspection. This raised concerns linked to consistency and continuity, in particular on the way that these findings would inform, support and direct Veterinary Auditors during the continuous official controls programme interventions in this establishment.
- 3.25 We recognise the unannounced element of official controls as a tool in verifying HACCP-based procedures, and the commitment by Operational Delivery in its implementation across all those establishments without daily officers attendance. The auditors, do, however, consider that some of the processes involved, specifically those around liaison-communication, preparation and the overall definition of the scope/objective of these UAIs within the audit cycle, would benefit from a review which would improve effectiveness and consistency. See overall ([Recommendation 3](#)) related to UAIs.
- 3.26 [Article 12. Documented control procedures](#)
- 3.27 Staff's operational procedures were found up to date and extensive. Guidance, both Domestic and European / International, provided in the SMOC through links

- and annexes was highly relevant to the subject audited at the officer level and also served as useful advisory aids for FBOs.
- 3.28 Operational management records for the overall delivery and monitoring of the audit programme are in place and found to be adequate in format and content, effectively directing the programme and informing decision-making. In particular, the auditors recognised the development of the Audit & UAI spreadsheet and the excellent work seen in its maintenance.
- 3.29 Regular documented meetings are taking place at different operational management levels. Monitoring of the audit programme as well as the level of compliance by FBOs with HACCP based procedures requirements appear to be extensive and adequate for their purpose as per evidence reviewed.
- 3.30 Findings indicated potential areas for improvement regarding the lack of participation of UAI officers in regular Veterinary Auditors meetings. The auditors acknowledge the operational and logistical difficulties in organising this but consider that there would be clear benefits. Broadening the forum to include all involved in delivery of the audit programme to discuss operational issues would enhance teamworking, engagement, consistency and confidence in all areas of the official controls programme, including the assessment of conformity with HACCP based principles.
- 3.31 Annual assessments of UAI officers delivering this task have not been taking place at the frequency stated in the Operational Internal Monitoring Policy. We consider this should be reinstated as per the planned arrangements. See overall ([Recommendation 3](#)) below related to UAIs.

Recommendation 3 (Unannounced Inspections (UAIs))

We would recommend reviewing the UAI process to ensure these support the Veterinary Auditors during the audit cycle as required by the planned arrangements.

- 3.32 [Article 13. Written records of official controls.](#)
- 3.33 Records and outcomes of the audit interventions are captured in one single document named the Establishment Live Report (ELR). This includes a dedicated section for the “HACCP system” as well as other sections for different systems that are also considered to be based on HACCP principles.
- 3.34 There is evidence of continuous improvement in the structure and content of these ELRs, with the current version being version 10. The HACCP system section comprises 15 subsections for assessment and verification, covering all 7 principles.
- 3.35 Random checks on ELRs across all operational areas were checked and found to be well completed with generally satisfactory but with varying levels of evidence recorded. These live documents are available to all members of Operational Delivery through SharePoint.

- 3.36 These reports are made available to the FBOs through email communication. Brief summaries of them are also published on the FSS website for transparency.
- 3.37 OVs in full attendance slaughterhouses are required to maintain records and evidence of checks directed at the assessment and verification of FBO's HACCP Plan and procedures based on HACCP principles. These checks are to be conducted according to the established frequency outlined in the SMOC, and aiming to provide evidence of compliance by the FBOs and inform other FSS staff members for continuity. The auditors found varying degrees of completion, with the less compliant being those slaughterhouses covered by non FSS employed staff. We acknowledge that action in this area is ongoing as part of recommendation made in the previous internal audit on Specified Risk Material Controls and Verification in QI 2024/25 programme, and it is being addressed.
- 3.38 [Article 138. Actions in the event of established non-compliance](#)
- 3.39 Enforcement procedures and policy embedded in the SMOC are up to date and provide operational staff with clear guidance on this area of official controls.
- 3.40 An extract of enforcement actions across all FSS approved establishments showed an estimated 538 enforcement actions related at least in part to HACCP have been taken by officers since October 2022. These include 181 interventions, 321 verbal advice, 33 written advice, 1 Remedial Action Notice, and 2 Food Detention Notices.
- 3.41 This positions the HACCP system as the second most enforced system by operational field staff. While no opinion has been given on the severity of these non-compliances, it was noted that the percentage of non-compliances assessed as "major" has decreased as the period reviewed progressed.
- 3.42 Figures of monthly HACCP enforcement entries are available at the management level via the Key Performance Indicator dashboard, allowing trends to be monitored to inform further decision-making.
- 3.43 The auditors agreed with the level of enforcement action taken on HACCP based procedures in the two establishments selected following the verification reality checks visits. Two minor non compliances were enforced and discussed for corrective action in one of these establishments.

Food Business Operator's feedback

- 3.44 The Audit team had the opportunity to meet FBO representatives in the two establishments selected for reality checks. The main points of this general feedback are detailed below.

- 3.45 In both occasions the FBOs gave a positive feedback of the current delivery approach to assess their Food Safety Management System. They agreed that this has facilitated a more focussed and targeted manner to verify compliance, particularly in the assessment of the verification, validation and implementation of the HACCP Plan and procedures based on it.
- 3.46 They valued the unannounced element of these official controls and supported its continuity.
- 3.47 In relation to Objective Connect they both recognised the benefits around the concept, however they expressed some difficulties in understanding the expectations on the volume of documentation to be uploaded and the ability to delete documents. At the moment they find the whole process time consuming with limited perceived benefits. Consequently, one establishment is attempting to comply, while the other is not prioritising this task.

4.0 Annex A – Action Plan

Action Plan for Operational Delivery Division – Official Controls of procedures based on HACCP Principles. Sep-Dec 2024

Recommended Point for Action	Planned Actions	Target Date for Completion	Responsible Officer(s)
<p>1. Review of the current gap intervals between the end and commencement of each audit cycle to ensure consistency with planned arrangements.</p> <p>Priority: Low</p>	<p>The Audit Operational Guidance will be reviewed to clarify the methodology in setting up the audit cycles and staff involved in delivering any audit-related inspections will be trained in the updated procedures.</p>	30 June 2025	<p>Joan Bricall Giuseppe Ragona Elena McWatt</p>
<p>2. Review the use of Objective Connect/eRDM at both FSS and FBO levels to enhance the efficiency and potentially effectiveness of processes directed at verifying FBO procedures based on HACCP principles.</p> <p>Priority: Medium</p>	<p>FBO guidance in the use of Objective Connect will be reviewed and enhanced with clearer expectations in relation to required documentation to be uploaded and FSS UAI officers will be given a refresher training in the use of eRDM for the purpose of audits.</p>	30 June 2025	<p>Joan Bricall Giuseppe Ragona Elena McWatt</p>
<p>3. We would recommend reviewing the UAI process to ensure these support the Veterinary Auditors during the audit cycle as required by the planned arrangements.</p> <p>Priority: High</p>	<p>Regular standardisation meetings involving the UAI officers and Vet Auditors will be set up, where feedback will be gathered and actioned and any changes in processes will be explained. A template agenda will be drafted in order to provide some structure, however the idea for these</p>	30 June 2025	<p>Giuseppe Ragona Elena McWatt</p>

Recommended Point for Action	Planned Actions	Target Date for Completion	Responsible Officer(s)
	<p>meetings will be kept rather informal, to stimulate discussion from staff not necessarily used to remote meetings.</p> <p>The Internal Monitoring Policy will be followed in relation to regular assessments of the UAI inspectors' performance.</p>		

All actions were completed following the receipt of evidence from Operational Delivery Division.

Audit has been closed in April 2026.

5.0 Annex B – HACCP Plan and Principles

The Codex Alimentarius outlines a systematic approach to developing a HACCP plan, which includes 12 steps. These steps are divided into 5 preliminary steps and the 7 HACCP principles stated in Article 5 of Regulation (EU) 853/2004.

Preliminary Steps:

1. **Assemble the HACCP Team:** Gather a multidisciplinary team with the necessary expertise.
2. **Describe the Product:** Provide a detailed description of the product, including ingredients and processing methods.
3. **Identify the Intended Use and Consumers:** Define the product's intended use and target consumers.
4. **Construct a Flow Diagram:** Create a flow diagram that outlines all steps in the process.
5. **On-Site Confirmation of Flow Diagram:** Verify the flow diagram by conducting an on-site review of the operation.

HACCP Principles:

1. **Conduct a Hazard Analysis:** Identify and evaluate potential hazards that could affect food safety.
2. **Determine Critical Control Points (CCPs):** Identify points in the process where control is essential to prevent or eliminate hazards.
3. **Establish Critical Limits for Each CCP:** Set maximum or minimum values to ensure each CCP is under control.
4. **Establish Monitoring Procedures:** Develop procedures to monitor CCPs and ensure they remain within critical limits.
5. **Establish Corrective Actions:** Define actions to be taken when monitoring indicates a CCP is not under control.
6. **Establish Verification Procedures:** Implement procedures to verify that the HACCP system is working effectively.
7. **Establish Documentation and Record-Keeping:** Maintain documentation and records to demonstrate the effective application of these steps and principles.

6.0 Annex C – Assurance Categories

Definition of Assurance Categories

<p>Substantial Assurance</p> <p>Controls are robust and well managed</p>	<p>Risk, governance and control procedures are effective in supporting the delivery of any related objectives. Any exposure to potential weakness is low and the materiality of any consequent risk is negligible.</p>
<p>Reasonable Assurance</p> <p>Controls are adequate but require improvement</p>	<p>Some improvements are required to enhance the adequacy and effectiveness of procedures. There are weaknesses in the risk, governance and/or control procedures in place but not of a significant nature.</p>
<p>Limited Assurance</p> <p>Controls are developing but weak</p>	<p>There are weaknesses in the current risk, governance and/or control procedures that either do, or could, affect the delivery of any related objectives.</p> <p>Exposure to the weaknesses identified is moderate and being mitigated.</p>
<p>Insufficient Assurance</p> <p>Controls are not acceptable and have notable weaknesses</p>	<p>There are significant weaknesses in the current risk, governance and/or control procedures, to the extent that the delivery of objectives is at risk. Exposure to the weaknesses identified is sizeable and requires urgent mitigating action.</p>

7.0 Acknowledgements

The Audit Assurance Team would like to acknowledge the help and co-operation of all staff involved for their assistance while conducting this audit.

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Food Standards Scotland

Audit Assurance Branch

April 2026

Abbreviations

AO	Authorised Officer
ELR	Establishment Live Report
eRDM	Electronic Record and Documentation Management System
FBO	Food Business Operator
FSA	Food Standards Agency
FSS	Food Standards Scotland
HACCP	Hazard Analysis and Critical Control Points
MHI	Meat Hygiene Inspector
OCR	Official Controls Regulation
OCV	Official Controls Verification
OV	Official Veterinarian
SMOC	Scottish Manual for Official Controls
UAI	Unannounced Inspection